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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,793	07/08/2005	Alexander Domling	62661(52171)	9957
21874 7590 01/13/2010 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
CHANG, CELIA C				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
01/13/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,793

Applicant(s)

DOMLING ET AL.

Examiner

Celia Chang

Art Unit

1625

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 19-23, 25-28, 30 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) 37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-23, 25-28, 30-34, 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This application is a RCE of SN 10/520,793.

Amendment and response filed by applicants dated Nov. 17, 2009 have been entered and considered carefully.

Claims 1-18, 24, 29, 35-36 have been canceled. Claims 19-23, 25-28, 30-34, 39 are pending. Claims 37-38 stayed withdrawn.

2. Claims 19-23, 25-28, 30-34, 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds wherein $n=4$, piperidinyl compounds, does not reasonably provide enablement for the compounds as now claimed wherein $n=2, 3$, or 5 , i.e. $4, 5$ or 7 membered ring compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Starting material and how to make the non-piperidinyl compounds such as formula IV nonpiperidinyl, are not seen but required. Absent of starting material, the public is offered mere language rather than enablement. In re Howarth 210 USPQ 689. Ex parte Moersch 104 USPQ 122.

Applicants argued that the compounds can be made with commercially available "amino acids". Please note that the term "amino acid" are ordinarily referred to the naturally occurring amino acids. Please note that the $n=4$ compounds using piperidine is not a naturally occurring amino acid but starting material is available. Proline is available but $n=2$ or $n=5$ starting material must be provided. Even if the compounds can be made, the specification must also provide description and enabling guidance that all diverse ring compounds can provide the how to use requirement with reasonable enabling support. In re Fisher 166 USPQ 18, 20 has set forth that the more unpredictable the field of activity, more enablement by way of *specific* examples is necessary in order to establish the broad utility of Markush compounds. In the highly unpredictable field of endeavor of treating cancer using chemical compound, the instant specification exclusively described only $n=4$ compounds lacks sufficient variation of ring compounds to establish support for the broad scope.

It is well recognized in the art that cancer treatment is structural sensitive and cancer specific, that is, specific compounds can treat specific cancer. The national cancer institute has provided guidelines that for compounds to have broad "antiproliferation" activity, one compound from each category of the cancer panel should be active (see p.628). In the instant case, only $n=4$, piperidinyl compounds have been shown to have inhibitory activity against carcinoma (see ACTT description). Nowhere in the specification that such breadth of compounds from 4 to 7 membered ring would have efficacy in treating *colon cancer, breast cancer, ovarian cancer epidermoid cancer or prostate cancer* of **all origin and cell type**. Please note that the cell lines tested are exclusively adenocarcinoma of the colon, breast, ovary, epidermis or prostate. No description or factual evidence that a specific piperidinyl compound effective in colon, breast, ovarian, epidermal or prostate adenocarcinoma would provide treatment of any other cancer type.

Therefore, for claims 19-23, 25-28, 30-34, 39 the scope of enablement on how to make $n=2, 5$ compounds or how to use the $n=2,3,5$ compounds are rejected. For claims 37-38, a rejoinder cannot be made due to the lack of descriptive and enabling support that the breadth of the compounds would have efficacy for all cancer of the colon, breast, ovary, epidermis or prostate.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan 7, 2010

/Celia Chang/
Primary Examiner
Art Unit 1625